

09/720604
PCT/AU99/00514



AV 99/00514

REC'D 03 AUG 1999
WIPO PCT

5
S
Patent Office
Canberra

I, KIM MARSHALL, MANAGER PATENT OPERATIONS, hereby certify that the annexed is a true copy of the Provisional specification in connection with Application No. PP 4374 for a patent by ASTRAPAK LIMITED filed on 29 June 1998.

**PRIORITY
DOCUMENT**

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

WITNESS my hand this Twenty-first
day of July 1999

KIM MARSHALL
MANAGER PATENT OPERATIONS



AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: **PLUG AND GLAND ASEPTIC PACKAGE SYSTEM**

The invention is described in the following statement:

To achieve filling rates of this order relatively large diameter filling inlets are required into the containers and the flap system disclosed in US Patent 4,805,378 limits the diameter and flow rate into the container. Also, for highly viscous materials, and for materials which contain solid particles, the flap system is not always completely suitable.

- 5 The US Patent 4805378 discloses a container which is filled via an upstanding plastics collar, at one end of which a first flange is heat fused to the flexible plastic sheet wall of the container surrounding a filling opening in the container and, at a second flange at the opposite end of the collar, a rupturable sheet plastics membrane is also heat fused. The sheet plastics membrane, which is heat sterilised in manufacture but which most likely would be recontaminated
- 10 externally before filling, is resterilised immediately prior to filling by a fluid (for example pressurised steam) after being brought into engagement with a filling head of an aseptic filler. In the described method, an incision tool forming part of the filling head, sterilised along with the exterior of the membrane, is advanced to cut the membrane then withdrawn to enable admission of the liquid to be packaged through the collar and through gaps formed between the flap
- 15 partially heat fused to the flange inside the container.

- As disclosed in US Patent 4805378, the cutting of the resterilised membrane involves making a pair of straight incisions, crossed at right angles passing through the centre of the membrane and extending radially outward to a point just inside the outer flange of the upstanding plastics collar. Accordingly, as the liquid or liquid-like product flows into the bag to fill it, the four cut tips or "reversed petals" of the membrane turn inwardly with the flow and extend towards the inner end of the collar where it is connected to the bag in the region that is subsequently sealed closed as described. There are occasionally experienced instances of unreliability with this arrangement in that the four petals of the top membrane, since they remain on the filled sealed package, are difficult to clean underneath to remove remnants of the packaged product inside of
- 20 the collar during the flushing cycle. Also, the petals tend to reduce the flow rate of the product into the container during filling which can be disadvantageous from a production point of view with viscous or particulate containing products.
- 25

- There is furthermore a risk that the tips of the petals might wrap underneath the inside corner of the flange and be caught up in the subsequent final heat sealing operation. If this were to happen
- 30 there would be a potential for a leakage path to bypass the seal or, at least, a potential source of

into the passage, the tubular body having an annular outer sealing face thereon which surrounds the flow passage, the method comprising the steps of:

- supporting the tubular body of the container in a selected orientation and position;
- providing a sterilisation and filling head having at least an outer sealing ring thereon which is adapted to engage and seal with the annular sealing face, and a sterilisation chamber located within the outer sealing ring;
- bringing the sterilisation and filling head and the tubular body into engagement with each other so that the outer sealing ring engages and seals with the annular sealing face;
- introducing a sterilisation fluid into the sterilisation chamber to sterilise at least the radially outer part of the plug and that part of the tubular body within the outer sealing ring;
- withdrawing the plug out of the tubular body in a direction away from the container whilst maintaining the sealing ring in sealed contact with the sealing face;
- introducing a flowable material into the container through the tubular body;
- reinserting the plug into the tubular body to thereby close the tubular body; and
- disengaging the sterilisation and filling head and the tubular body from each other.

The method may include the further steps of:

- providing the sterilisation and filling head with an inner sealing ring which is co-axial with the outer sealing ring, the sterilisation chamber being formed in the annular space between the two sealing rings;
- providing a plug with an annular sealing face thereon which is co-axial with the annular sealing face on the tubular body and is adapted to be engaged by the inner sealing ring;
- bringing the sterilisation and filling head and the tubular body into engagement with each other so that the outer sealing ring engages and seals with the annular sealing face on the body, and the inner sealing ring engages and seals with the annular sealing face on the plug; and
- introducing the sterilisation fluid into the annular sterilisation chamber.

- holding means for holding the container and/or the tubular body in a selected position;
 - a sterilisation and filling head having at least an outer annular sealing ring adapted to engage the annular sealing face on the tubular body, the sterilisation and filling head having a sterilisation chamber located inwards of the outer sealing ring, the sterilisation and filling head having a cavity therein adapted to receive the plug of a container to be filled, the sterilisation and filling head and/or the tubular body being movable towards and away from the other;
 - sterilisation fluid supply means adapted to supply sterilisation fluid to the sterilisation chamber;
- 5 10 10 • a plug extractor adapted to extract a plug from the tubular body and move the plug into the cavity in the sterilisation and filling head; and
- filling means adapted to fill the container through the sterilisation and filling head when the plug has been extracted.

Preferably the sterilisation and filling head includes an inner sealing ring which is co-axial with
15 said outer sealing ring and spaced inwardly therefrom to define an annular space therebetween,
said annular space forming said sterilisation chamber, said inner sealing ring being engageable
with a sealing face provided on the plug.

The plug extractor may comprise one or more gripping jaws adapted to grip the plug and extract
it from the tubular body into the cavity. The jaws may be mounted to a ram which is moveable
20 in an axial direction towards and away from the plug, the jaws being moveable between
gripping and release positions. Preferably the jaws automatically move to a gripping position
when the ram moves in a direction away from the plug, and move into the release position when
the ram moves towards the plug. The ram may be adapted to drive the plug into the tubular
passage after the container has been filled.

25 The sterilisation and filling head may be adapted to shut off the flow of filling material into the
container prior to the plug being fully inserted into the tubular passage. The sterilisation and
filling head may, furthermore, be adapted to clean the plug with sterilisation fluid when the plug
is partially re-inserted back into the tubular passage.

made to the accompanying drawings, but the specific feature shown in the drawings should not be construed as limiting on the invention. In this specification, where the words "comprising" or "comprised" are used, those terms are to be interpreted inclusively rather than exclusively.

Brief description of the drawings

- 5 Figure 1 shows a cross sectional half view through part of a container and the transfer port into the container according to the first embodiment of the invention, the other half view being a mirror image of figure 1.
- Figure 2 shows the cross sectional side view of a sterilisation head according to the invention in engagement with the port shown in figure 1;
- 10 Figure 3 shows a similar view to that of figure 2 with sterilisation fluid sterilising the outer surface of the transfer port;
- Figure 4 shows a similar view to that of figures 2 and 3 with the plug removed from the tubular body of the transfer port and with filling material being introduced to the container;
- 15 Figure 5 shows a similar view to that of figure 3 but with the inlet partially closed by the plug and with sterilisation fluid being used to flush and clean the plug;
- Figure 6 shows a similar view to that of figure 5 with the plug fully inserted into the tubular body;
- 20 Figure 7 shows the sterilisation and filling head and the transfer port separated from each other;
- Figure 8 shows a cross-sectional side view of a second embodiment of sterilisation and filling head with the transfer port in engagement with the head;
- Figure 9 shows a similar view to that of Figure 8 with the plug lifted out of the tubular body;
- 25 Figure 10 shows a similar view to that of Figures 8 and 9 with the plug partially closed; Figure 11 shows a similar view to that of Figure 8 but with the plug fully closed;

In order to commence the filling operation the sterilisation and filling head 39 and the upper surface of the transfer port 14 are brought into engagement with each other, as shown in figure 2. This is most conveniently done by gripping the transfer port with gripping jaws (not shown) and lifting the transfer port in the direction of axis 52 until the sealing faces 34 and 38 engage and seal with the sealing rings 40 and 42 respectively.

The sterilisation and filling head is provided with a sterilisation fluid supply line 54 which leads into the sterilisation chamber 44 and which is controlled by an inlet valve 56. A sterilisation fluid discharge line 58 leads from the sterilisation chamber 44 and is controlled by an exit valve 60. The sterilisation fluid will generally comprise steam supplied under pressure at a temperature of between 130°C and 180°C.

The inner sealing ring 42 is formed on the end of a sliding sleeve 64 which is slidable along axis 52 towards and away from the transfer port 14. The sliding sleeve 64 serves as a control valve for controlling the flow of a flowable product into the container, as is described in more detail below.

An axially moveable plunger or ram 62 is moveable along axis 52 within a cylindrical cavity 66 formed within the sleeve 64. The ram 62 has a series of gripping jaws 70 fitted to the end thereof which are spring loaded by means of a spring 74. The gripping jaws 70 are adapted to engage with the head 30 of the plug 22 in order to pull the plug 22 out of the tubular passage 19.

The sterilisation and filling head 39 is provided with a product supply passage 76 through which product to be filled into the container 10 is fed through the head. When the sleeve is retracted to the position shown in Figure 4 product will flow into the container through the passage 76.

In use, the apparatus operates substantially as follows. Firstly, the tubular body 16 is brought into engagement with the outer sealing ring 40 so that the blade edge 48 embeds into the sealing face 34. The tubular body 16 will be held under pressure against this blade edge 48 for the entire filling process so that a seal will be maintained. Simultaneously the inner blade edge 50 will bed into the sealing face 38 of the plug 22. At this stage the sterilisation cavity 44 will be a sealed cavity. It will be noted that the outer sealing ring 40 and the inner sealing ring 42 are located on opposite sides of the interface between the tubular body 16 and the plug 22.

In this position, the sterilisation head will be tightly clamped against the transfer port 14, and the ram 52 will be lifted causing the jaws 70 to clamp tightly around the head 30, thereby

Once the transfer port has been cleaned in the manner described and depicted in figure 5, the plug can be pushed further into the passage 19 as indicated in figure 6 of the drawings. It will be noted that the inner wall 18 of the tubular body has an annular groove 82 which lies just below the sealing surface 34. The plug has an outwardly directed lip 84 on its outer edge and when the 5 plug is pressed into the passage 19 so that the surface 38 lies below the surface 34 the lip 84 will locate in the groove 82 to provide a locking arrangement between the plug and the tubular body. Optionally the groove 82 may have an annular elastomeric seal 86 located therein and the lip 84 will engage with that seal 86 to form a bacteria proof sealing arrangement.

It will be noted that as the ram 52 moves the plug inwardly from the position shown in figure 5 10 to the position shown in figure 6 the jaws 70 will automatically disengage from the head 30 to allow the plug 22 to be pressed further into the tubular body 16.

It will be noted that towards the lower end of the sleeve 64 a tapered or bevelled sealing surface 88 is formed. This sealing surface 88 is adapted to engage and seal with a seat 90 which is defined within the sterilisation and sealing head just above the sterilisation chamber. When the 15 sleeve 64 moves to a closed position, as shown in Figure 5, the surface 88 will engage and seal with the seat 90 to form a fluid tight seal. It is envisaged that this seal will be a metal to metal seal or some other form of hard seal which will form a positive stop for the downward movement of the sleeve 64. This will allow the sleeve 64 to be moved up and down using pneumatics.

20 The hard seal will serve to sever or shear any particulate materials that might otherwise be trapped as the sleeve 64 moves to the closed position.

Clearly there may be many forms of interlocking arrangements which may be provided between the plug and the tubular body. What is important is that no micro passageway exists for the passing of micro organisms between the plug and the tubular body which could otherwise 25 compromise the integrity of the seal provided between the plug and the tubular body.

Alternative arrangements for sealing the plug in the tubular body include some form of welding system. For example, either the plug or the tubular body, or both, may be formed of a material which will soften in the presence of the high temperature sterilisation fluid and, when so softened, weld the plug and the tubular body together as the plug is fully inserted into the 30 tubular body to thereby form a seal between these two components which is bacteria proof. It

steam will serve to soften the outer surface of the plug. These two components will then weld together when the plug is in its closed position.

Turning now to Figure 12, Figure 13, Figure 14, Figure 15 and Figure 16 of the drawings, a sterilisation and filling head similar to the previous embodiment is shown which is also used to close off the flow of product into the container prior to the plug being fully closed.

In this embodiment, the sterilisation and filling head 98 has a moveable sleeve 100 which is used to lift the plug 22 out of the tubular body 16 and also serves to open and close the filling passage 76. The sleeve 100 is formed of an inner sleeve 102 and outer sleeve 104 which are moveable relative to each other. The inner sleeve 102 has a sharp lower edge 106 which is adapted to engage the sealing surface 38 on the plug 22. The outer sleeve 104 has a bevelled lower edge 108 which is arranged to engage and seal with the seat 90 of the sterilisation and filling head. A sliding seal 110 seals the gap 112 between the inner sleeve 102 and outer sleeve 104.

Illustrated in Figure 12, the ram 62 is shown in an extended position relative to the gripping jaws 70. This keeps tips 71 of the gripping jaws 70, which engage the undercut 32 of plug 22, in an unengaged position whereby the tips 71 are clear of the undercut 32.

As illustrated in figure 13, as the ram 62 is retracted, a flange 73 on its lower end engages an internal shoulder 75 on the jaws 70. This moves the jaws 70 axially away from the tubular body 16 which forces ramps 77 on each of the jaws 70 to engage ramps 79 on the inner sleeve 102.

This forces the tips 71 to engage the plug beneath the undercut 32.

In the condition illustrated in Figure 13 sterilisation fluid enters the sterilisation chamber 44 as in the embodiment of Figures 2 to 7 or 8 to 11.

Once sterilisation of the portions of the plug 22 and tubular body 16 which are exposed in sterilisation chamber 44 has been completed, the outer sleeve 104, inner sleeve 102 and ram 62 are retracted together with each of these items maintaining the positions relative to each other as illustrated in Figure 13.

Once the outer sleeve 104 has retracted to fully open the passage 76, as illustrated in Figure 14, the inner sleeve and plug 22 are potentially occluding the passage 76. If the opening is not sufficient, the inner sleeve 102 and ram 62 move together until such time as the upper surface of

Turning first to Figure 17, it will be noted that the plug 22 and transfer port 16 have a seal 114 therebetween which will seal off the gap 116 between the plug 22 and transfer port 16. The seal 114 will, it is envisaged, be adapted to melt, or at least soften when heated by the sterilisation fluid. Thus, when sterilisation of the transfer port 16 is taking place prior to the plug 22 being removed from the tubular body 16, the seal 114 being exposed to hot sterilisation fluid, will melt, and the plug 16 may thereafter be extracted from the tubular body 16. The seal 114 will, however, have ensured that no contaminating micro organisms could have entered into the gap 116 between the plug 22 and the tubular body 16.

A different seal arrangement is shown in the right hand side of the Figure 18 embodiment. In this arrangement an outer surface 119 of the plug 22 has a adhesive material 118 coated on the thereon which is adapted to bond to the inner surface 120 of the tubular body 16. Thus, when the outer surface 119 of the plug 22 is heated during the closure operation, as described above with reference to the second and third embodiments of the invention, this adhesive material 118 will soften so that when the plug 22 is closed, as shown in the Figure 18 drawing, adhesive 118 will bond to the surface 120. This will form a permanent bond between the plug 22 and tubular body 16 thereby ensuring that the seal between these two components will not be compromised after the container has been filled.

The embodiment shown in Figure 19 is similar to that shown in Figure 1. The seal is achieved by an elastomeric seal 122 which is located in a groove 124 formed in the inner wall of the tubular body 16. The elastomeric seal 122 may be adapted to bond with the outer wall of the plug 22, particularly where the plug 22 has been heated during the closing operation. The plug 22 also has a pair of outwardly directed ribs 126 which are located in corresponding grooves 128 formed in the inner wall of the tubular body 16.

In the embodiment shown in Figure 20, the plug 22 has a relatively deep skirt 130 having an outwardly directed flange 132 on the lower edge thereof and an outwardly directed flange 134 on the upper edge thereof which locates in a recess 136 formed in the tubular body 16. Provided the plug 22 is a tight sliding fit within the tubular body 16, the combined effect of the flange 132 and 134, and the lengthy face to face contact between the plug 22 and the tubular body 16 should ensure that the seal between the plug 22 and the tubular body 16 is not compromised. Also, the outwardly directed flange 132 will have a wiping effect as the plug 22 is inserted into

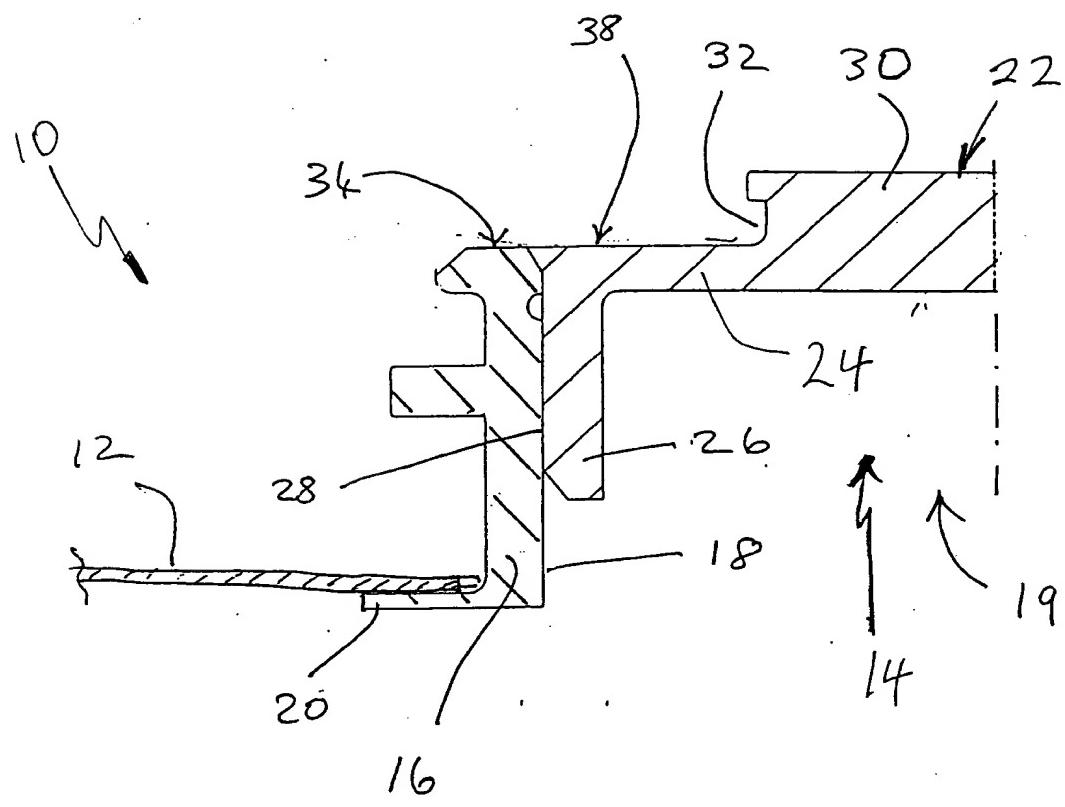
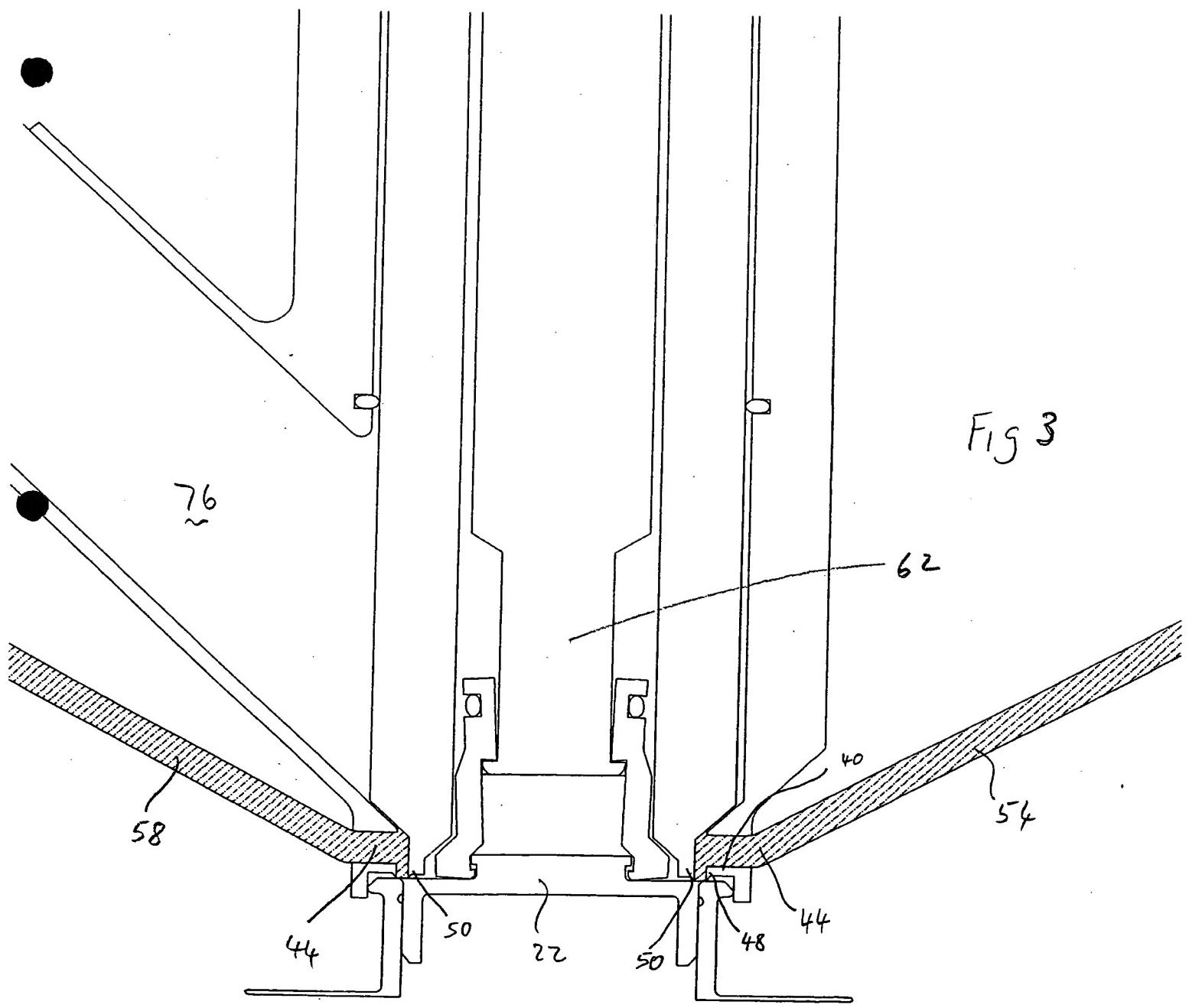
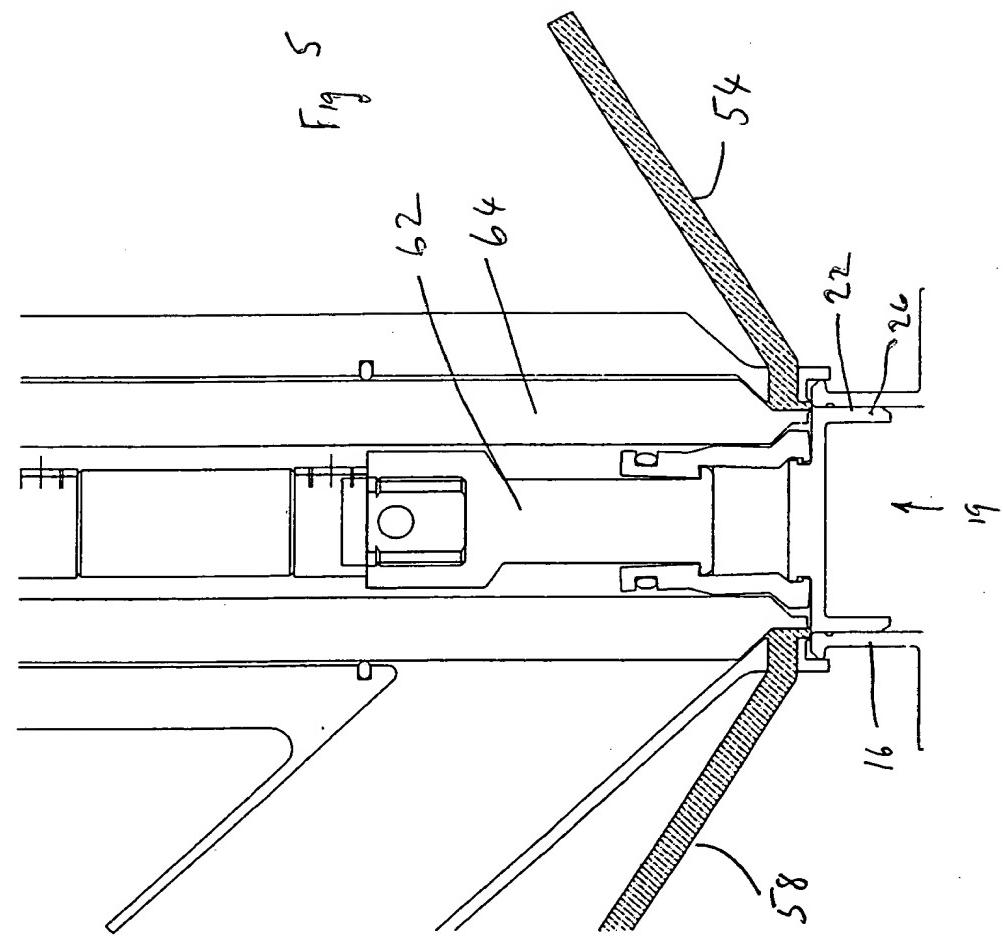
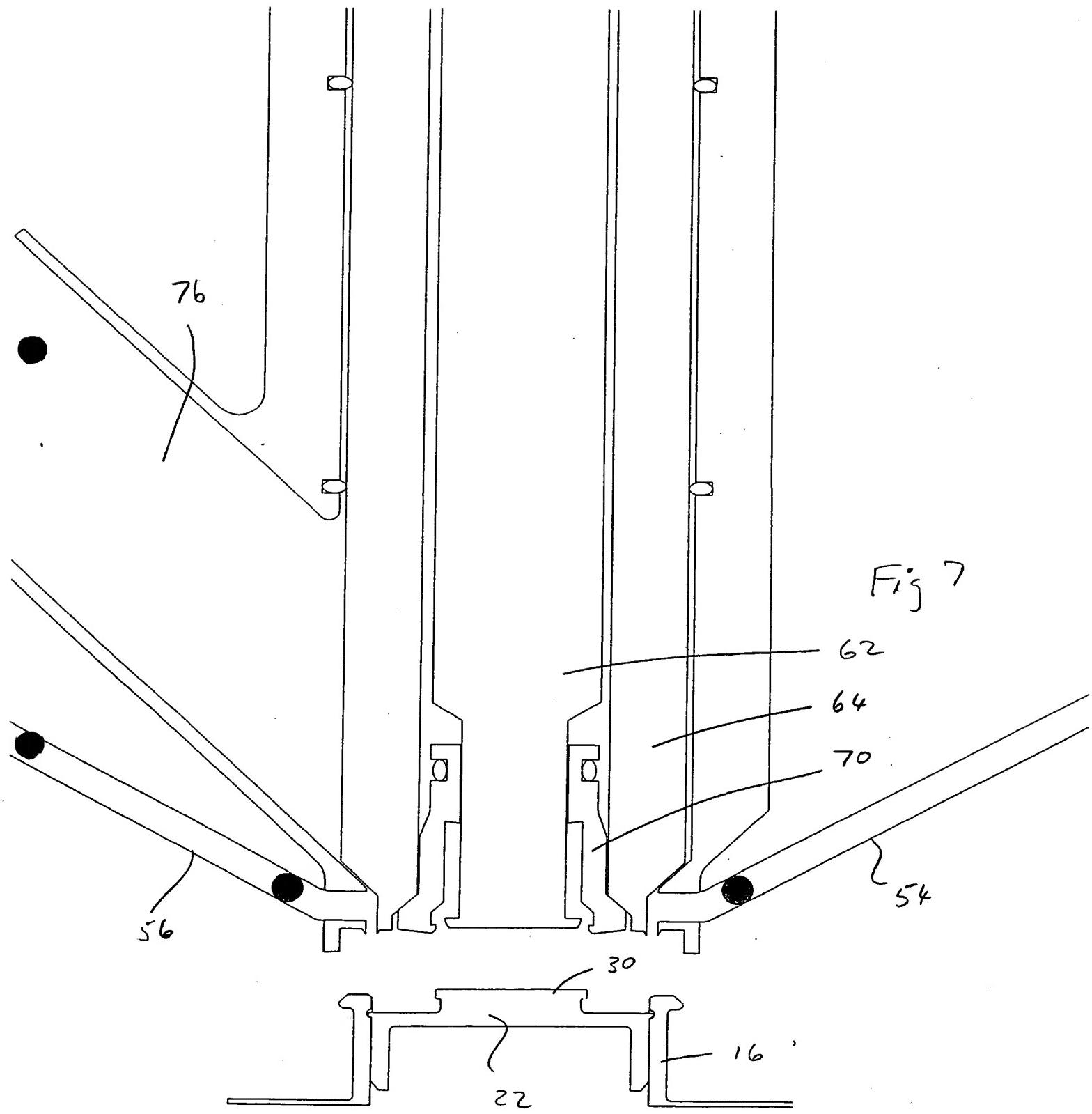


Fig 1







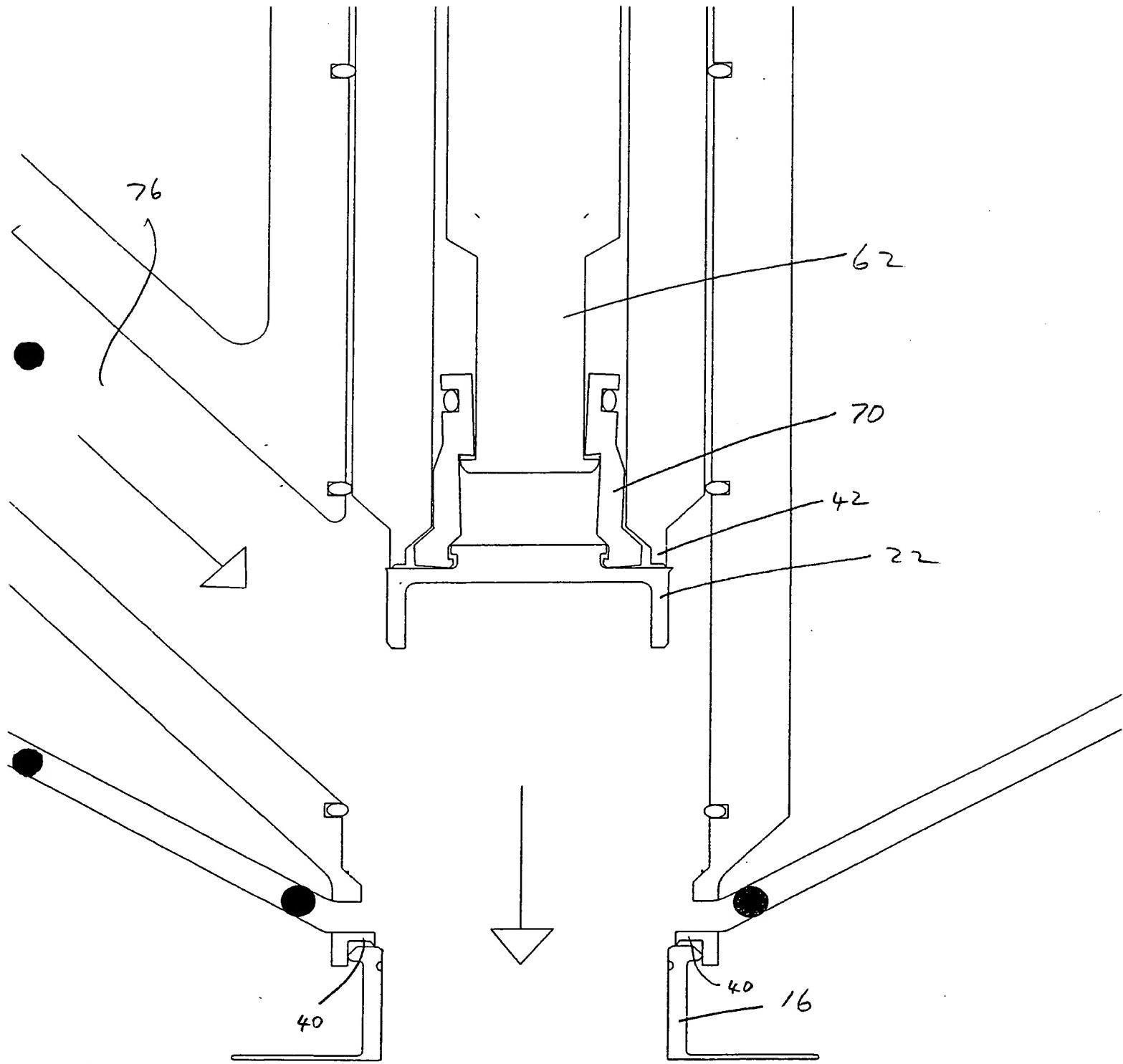


Fig 9

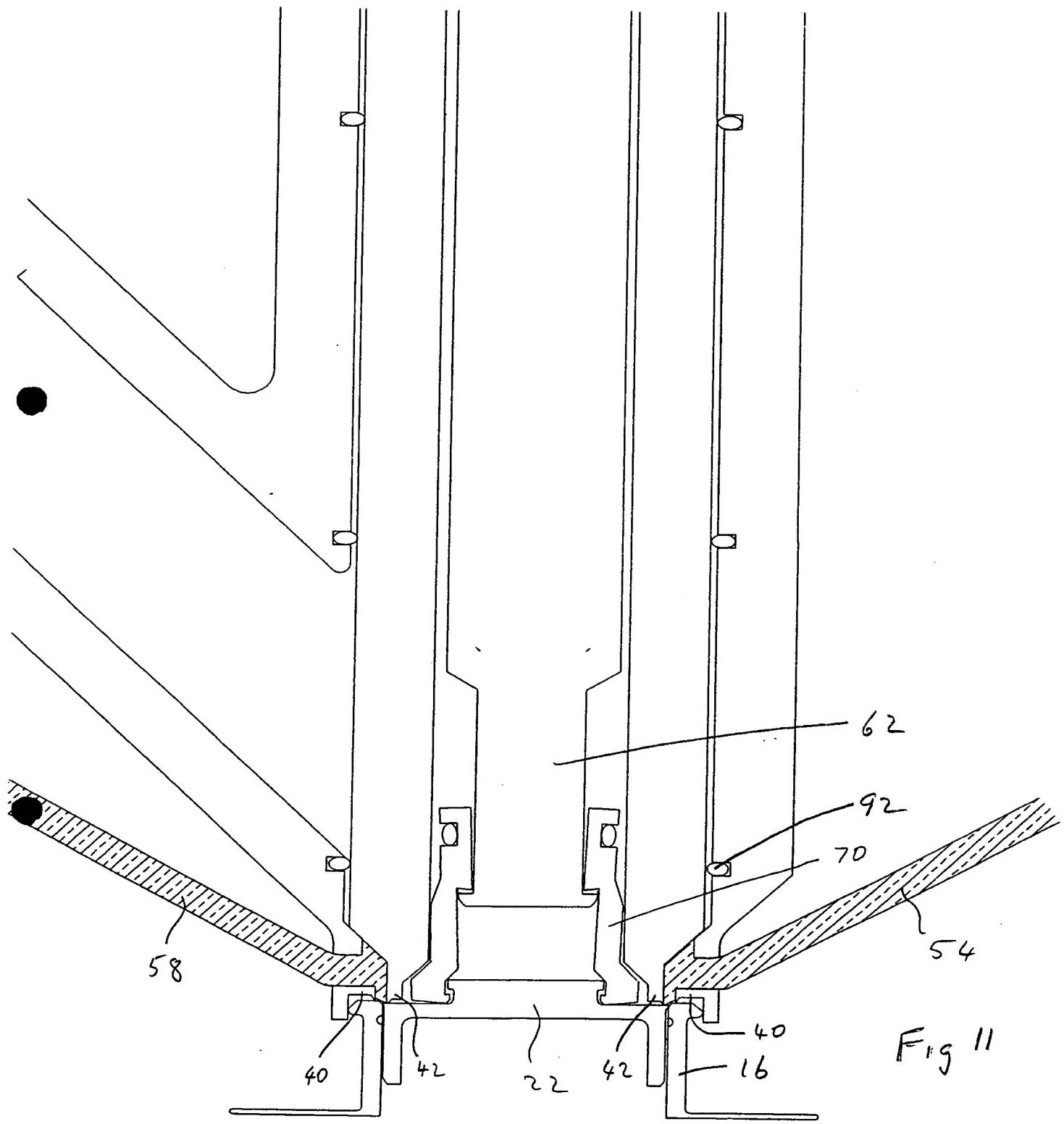


Fig 11

)

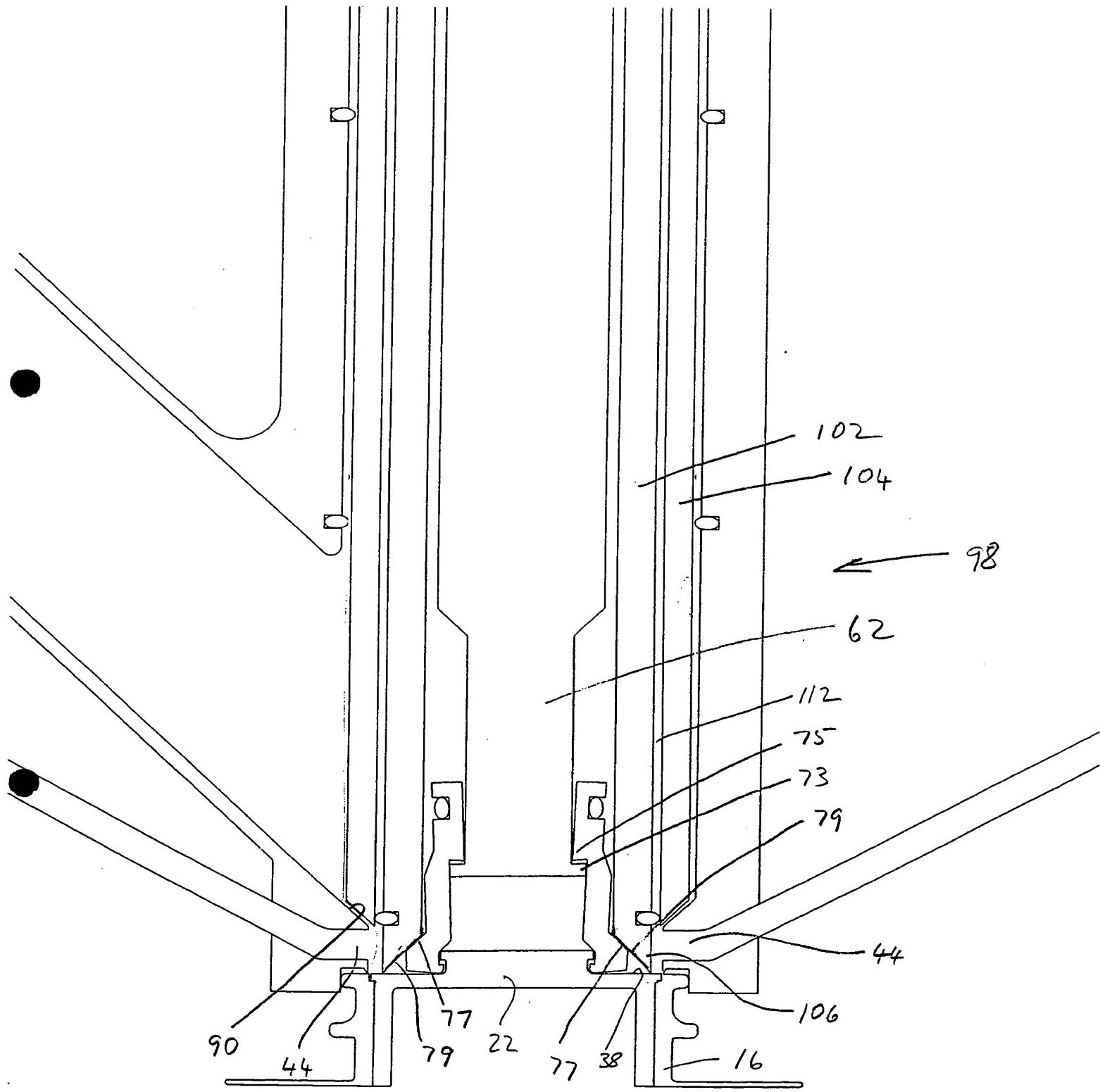


Fig 13

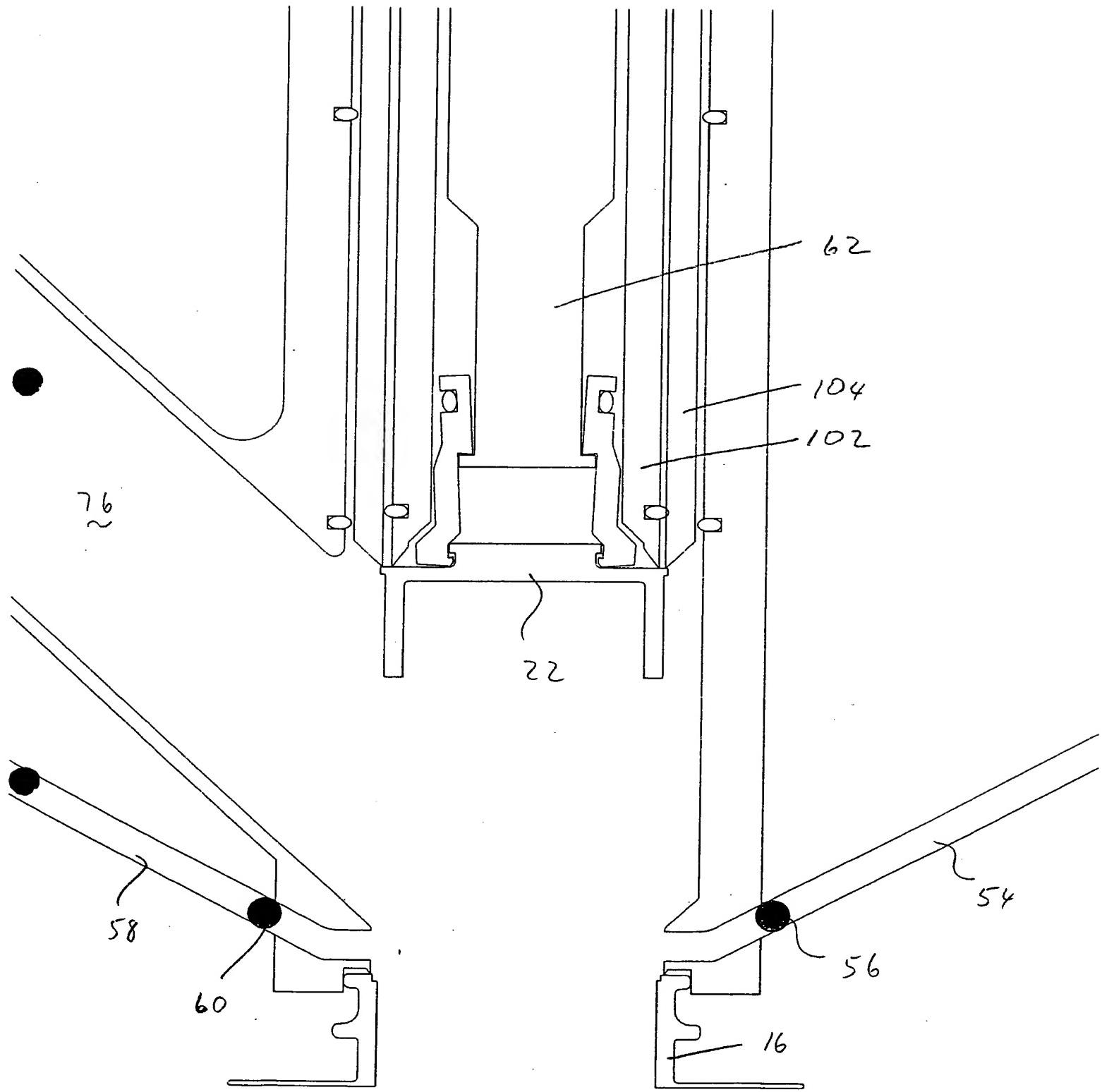


Fig 15

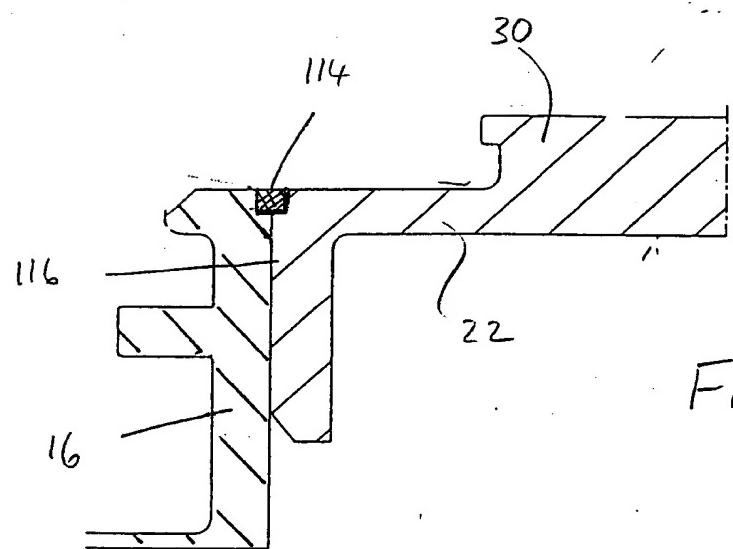


Fig 17

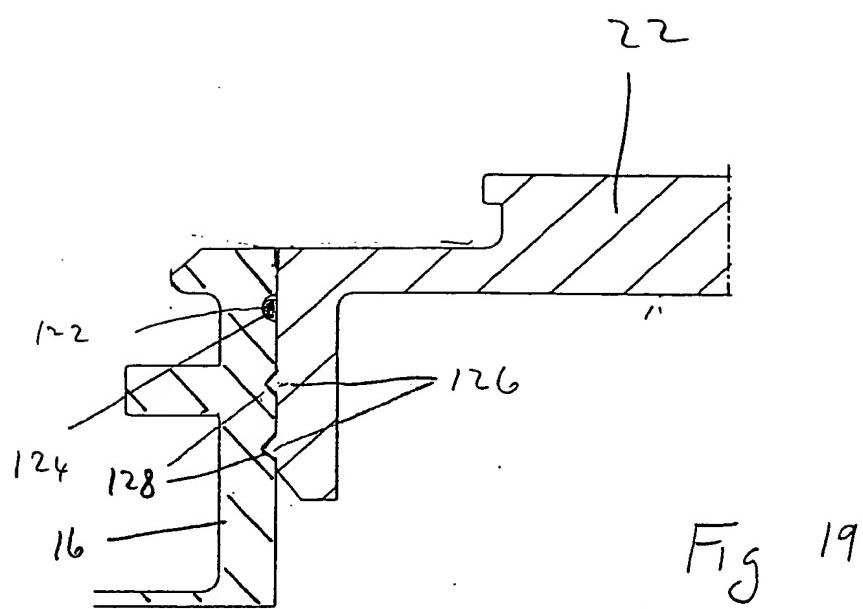


Fig 19